Informed Consent for Parents

On the AISD Department of Research and Evaluation’s external research internal review form it specifies that the following components in the parent consent form be checked and edited for:

Please check for the following on consent forms:

- Active consent (Parent must agree to student participation in the study, as opposed to passive consent, where parent returns the form only if they are denying permission...so anyone who does not return a form is assumed to have permission to participate.)
- < 6th-8th grade reading level – simply explains all components of the study
- Provided in English AND Spanish
- All data elements requested in the application are specified on the consent form
- Includes a place for parent to provide the Student ID if researcher is requesting a data pull
- If SES or Free/Reduced Price Lunch status is requested, DoE disclaimer language is included
- The most controversial survey item(s) or topic(s) are specified on the consent form
- Provides information about how to preview the survey (e.g., by contacting the researcher, or the researcher will make it available online or in the counselor’s office on the school campus)
- Describes data storage, report, and confidentiality procedures and policy
- Explains how data will be used (this is particularly important with multi-functional consent forms, such as those being used for both program participation and for the connected program evaluation).
- Explains what parents can do or who they can contact if they have any concerns or questions about the research or about the program.

- Be sure the consent form explains, up front, what is being offered and what is being asked (especially in the case of a program and evaluation):
  - Provide a title for the program as a header to the consent form, if it is longer than one page.
  - The very first paragraph should provide some information about the program. Who are you? What is the program? What will my child do as part of the program? How often? When? Where? Under whose supervision? What is the goal of the program? How long will the program continue? Will it cost me anything?
  - As part of the program, students will also be involved in a research study to determine whether this type of program is helpful to students. (Indicate whether a student can receive services if parents do not consent to the research study.)
  - Indicate what data will be used for what purpose, for examples:
    1. “Your student’s ID number will be used to track services provided to students and to evaluate the effectiveness of these services.”
    2. “Your student’s discipline referral history, <XYZ> assessment test scores, special education history, and the facilitator’s case notes regarding services provided to your child as well as classroom observations will be used to measure the effectiveness of the program.”
3. “All reports about the program will include aggregate information for all students who participate, and your child will not be named or identified individually in any report.”
   - Explain the information about how the data will be used and stored to protect confidentiality.
   - Explain any potential risks and benefits involved in the study.
**Peer Reviewed Findings about Informed Consent & Readability**

**Communicating with patients who have limited literacy skills. Report of the National Work Group on Literacy and Health.** Journal Family Practice 1998 Feb; 46(2):168-76.

Between 40 and 44 million persons in the United States have rudimentary literacy skills, and are unable to understand written materials that require only basic reading proficiency. The purpose of this report is to characterize the current status of illiteracy in the United States, describe the relationship between poor literacy and poor health, and make recommendations on how to deal with patients who have poor reading skills. Data collected by the National Work Group on Literacy and Health indicate that one quarter of the US population has rudimentary reading skills, and another 25% has limited reading skills. This makes it difficult to have written communication with much of the US population. Poor reading skills are associated with poor health and greater use of health services, but the basis for this association is unclear. Instruments are available to measure patients' reading skills in clinical settings, and information can be transmitted to patients in ways that make it understandable to poor readers. However, it is not known if using special low-literacy education materials with these patients improves health outcomes. When written communication with low-literacy patients is essential, materials should be at the 5th-grade level or lower, supplemented by nonwritten communication. Simple and nonwritten materials are appropriate for persons with limited literacy, and also for those with well-developed literacy. Research is needed to clarify the mechanisms through which illiteracy influences health status and health services utilization, and to determine if using low-literacy health education materials improves health outcomes.


Data collected through this small pilot study suggest several preliminary but potentially important findings when working with adults from low-income populations: First, while all participants read some parts of the consent forms (55%), only a minority reported reading the entire form (45%); second, 73% of participants reported understanding the study very well whereas only 27% reported understanding the study "a little"; third, there was a reported advantage of the simplified form over the regular form; however, this difference varied by section. Relatedly, other research has shown a high incidence of persons reading none of the consent form, but signing a statement that they have read and understood the study.


Patients who misunderstand their diagnosis and treatment plans usually exhibit poor compliance. The 90 million adult Americans with low literacy skills struggle to understand such essential health information as discharge instructions, consent forms, oral instructions and drug labels. The Joint Commission on Accreditation of Health Organizations (JCAHO) now requires that instructions be given on a level understandable to the patient. Most
physicians tend to give too much information on too high a level for many patients to understand. Physicians who speak in simpler language, repeat their instructions and demonstrate key points, while avoiding too many directives, enhance their patients' understanding. Combining easy-to-read written patient education materials with oral instructions has been shown to greatly enhance patient understanding. To be effective with patients whose literacy skills are low, patient education materials should be short and simple, contain culturally sensitive graphics and encourage desired behavior.


Patient and employee illiteracy is a problem that health care managers must deal with. More than half of all Americans may be unable to read and understand written materials used in hospitals, clinics, and other health care facilities. There is a mismatch between employees' and patients' reading level and the reading level of most written materials used by health care facilities. This can lead to noncompliance with treatment, missed appointments, wrong dosage of medications, uninformed consent, and undo fear among patients.


RESULTS: The average reading level of all consent forms was high: 12.2, which corresponds roughly to a 12th-grade reading level. Less than 10% of all consent forms were written at a 10th grade reading level or below. Thirty-two percent of all consent forms had no evidence of revisions, and less than 2% of consent forms were revised more than once. Readability scores were not related to consent form revisions, the type of IRB, the year of study, or the university where the research was conducted.

CONCLUSIONS: Poor readability of consent forms probably occurs in all university-related research. We recommend that IRBs require readability checks for research consent forms before researchers submit their proposals to an IRB.


RESULTS: Seventy-six informed consent forms were evaluated, and neither the Fry score or the RPF score was in the target range. Ninety-six percent of the forms were found to have readability levels higher than the target level (8th grade). The mean readability and processability score was 46, resulting in the classification, Minimally Adequate/Needs Improvement. (The target range was Good, 61-100.) A question by question analysis of each of the 20 checklist items on the RPF identified important aspects of text writing style that were scored as Unacceptable or Poor.

For many patients, lack of literacy skills is a major obstacle to effective health care communication. On average, 20% of the adult population in the United States has low literacy skills or reads at or below the fifth-grade level.

Note Table 1 (below)

<table>
<thead>
<tr>
<th>Readability Level</th>
<th>Voluntary Participation</th>
<th>New Information about Risks</th>
<th>No Direct Benefits</th>
<th>Involuntary Removal</th>
</tr>
</thead>
<tbody>
<tr>
<td>4th Grade†</td>
<td>“You don’t have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor’s attitude toward you will not change.”</td>
<td>“We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study.”</td>
<td>“There is no benefit to you from being in the study. Your taking part may help patients in the future.”</td>
<td>“You may be taken out of the study if: 1. Staying in the study would be harmful. 2. You need treatment not allowed in this study. 3. You fail to follow instructions. 4. You become pregnant. 5. The study is canceled.”</td>
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<tr>
<td>6th Grade†</td>
<td>“Taking part in this study is your choice. If you decide not to take part, this will not harm your relations with your doctors or with the University.”</td>
<td>“We may learn new things during the study that you may need to know. We can also learn about things that may make you want to stop participating in the study. If so, you will be notified about any new information.”</td>
<td>“You may receive no direct benefit from being in this study. However, your taking part may help patients get better care in the future.”</td>
<td>—§</td>
</tr>
<tr>
<td>8th Grade†</td>
<td>“Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.”</td>
<td>“We will tell you about new information that may affect your willingness to stay in this study.”</td>
<td>“There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.”</td>
<td>“The study doctors have the right to end your participation in this study for any of the following reasons. It would be dangerous for you to continue. You do not follow study procedures as directed by the study doctors. The sponsor decides to end the study.”</td>
</tr>
<tr>
<td>10th Grade†</td>
<td>“Your participation in this study is voluntary and you are free to withdraw at any time. Participation or withdrawal will not affect any rights to which you are entitled.”</td>
<td>“We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.”</td>
<td>“There is no guarantee that you will receive direct benefit from your participation in this study.”</td>
<td>“The study doctor, or the sponsor, may stop my participation in this study without my consent.”</td>
</tr>
<tr>
<td>12th Grade†</td>
<td>“Your participation in this study is strictly voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without prejudice to your future health care or other services to which you are otherwise entitled.”</td>
<td>“You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate. If new information becomes known that will affect you or might change your decision to be in this study, you will be informed by the investigator.”</td>
<td>“There may be no direct benefit to me, however, information from this study may benefit other patients with similar medical problems in the future.”</td>
<td>“You may be terminated from this study without your consent if you have serious side effects, you fail to follow your doctor’s instructions, your disease gets worse, or the sponsor closes the study. If this should happen, your doctor can discuss other available treatment options with you.”</td>
</tr>
<tr>
<td>College¶</td>
<td>“You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University.”</td>
<td>“During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.”</td>
<td>“The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study.”</td>
<td>“Your participation in this research project may be terminated by your doctor without your consent if you are not benefiting from the treatment, or if the treatment/protocol is determined to be inappropriate to your case. You may also be terminated from participation at any time, at the study physician’s discretion, for any reason he/she deems appropriate.”</td>
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* All the examples are taken directly from medical-school Web sites unless otherwise noted.
† The readability level is based on the Flesch–Kincaid readability scale.
‡ The passage was modified to present key concepts at a 4th-grade reading level.
§ No passage was found at this reading level.
¶ The readability level is based on the Fry readability formula.